UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS Subcategory Case No. 03-10643
THIS DOCUMENT RELATES TO: *The City of New York v. Abbott Labs., et al.* (S.D.N.Y. No. 04-CV-06054) *County of Nassau v. Abbott Labs., et al.* (E.D.N.Y. No. 04-CV-05126) and other cases listed on the following page	Judge Patti B. Saris Magistrate Judge Marianne B. Bowler

DEFENDANT MERCK & CO., INC.'S OPPOSITION
TO PLAINTIFFS' MOTION TO COMPEL

THIS DOCUMENT RELATES TO:)	*County of Herkimer v. Abbott Labs., et al.*)
County of Westchester v. Abbott Labs., et al.)	(N.D.N.Y. No. 05-CV-00415))
(S.D.N.Y. No. 03-CV-6178))	*County of Oneida v. Abbott Labs., et al.*)
County of Rockland v. Abbott Labs., et al.)	(N.D.N.Y. No. 05-CV-00489))
(S.D.N.Y. No. 03-CV-7055))	*County of Fulton v. Abbott Labs., et al.*)
County of Putnam v. Abbott Labs., et al.)	(N.D.N.Y. No. 05-CV-00519))
(S.D.N.Y. No. 05-CV-04740))	*County of St. Lawrence v. Abbott Labs., et al.*)
County of Dutchess v. Abbott Labs., et al.)	(N.D.N.Y. No. 05-CV-00479))
(S.D.N.Y. No. 05-CV-06458))	*County of Jefferson v. Abbott Labs., et al.*)
County of Orange v. Abbott Labs., et al.)	(N.D.N.Y. No. 05-CV-00715))
(S.D.N.Y. Case No. 07-CV-2777))	*County of Lewis v. Abbott Labs., et al.*)
County of Washington v. Abbott Labs., et al.)	(N.D.N.Y. No. 05-CV-00839))
(N.D.N.Y. No. 05-CV-00408))	*County of Chautauqua v. Abbott Labs., et al.*)
County of Rensselaer v. Abbott Labs., et al.)	(W.D.N.Y. No. 05-CV-06204))
(N.D.N.Y. No. 05-CV-00422))	*County of Allegany v. Abbott Labs., et al.*)
County of Albany v. Abbott Labs., et al)	(W.D.N.Y. No. 05-CV-06231))
(N.D.N.Y. No. 05-CV-00425))	*County of Cattaraugus v. Abbott Labs., et al.*)
County of Warren v. Abbott Labs., et al.)	(W.D.N.Y. No. 05-CV-06242))
(N.D.N.Y. No. 05-CV-00468))	*County of Genesee v. Abbott Labs., et al.*)
County of Greene v. Abbott Labs., et al.)	(W.D.N.Y. No. 05-CV-06206))
(N.D.N.Y. No. 05-CV-00474))	*County of Wayne v. Abbott Labs., et al.*)
County of Saratoga v. Abbott Labs., et al.)	(W.D.N.Y. No. 05-CV-06138))
(N.D.N.Y. No. 05-CV-00478))	*County of Monroe v. Abbott Labs., et al.*)
County of Columbia v. Abbott Labs., et al.)	(W.D.N.Y. No. 05-CV-06148))
(N.D.N.Y. No. 05-CV-00867))	*County of Yates v. Abbott Labs., et al.*)
Essex County v. Abbott Labs., et al.)	(W.D.N.Y. No. 05-CV-06172))
(N.D.N.Y. No. 05-CV-00878))	*County of Niagara v. Abbott Labs., et al.*)
County of Chenango v. Abbott Labs., et al.)	(W.D.N.Y. No. 05-CV-06296))
(N.D.N.Y. No. 05-CV-00354))	*County of Seneca v. Abbott Labs., et al.*)
County of Broome v. Abbott Labs., et al.)	(W.D.N.Y. No. 05-CV-06370))
(N.D.N.Y. No. 05-CV-00456))	*County of Orleans v. Abbott Labs., et al.*)
County of Onondaga v. Abbott Labs., et al.)	(W.D.N.Y. No. 05-CV-06371))
(N.D.N.Y. No. 05-CV-00088))	*County of Ontario v. Abbott Labs., et al.*)
County of Tompkins v. Abbott Labs., et al.)	(W.D.N.Y. No. 05-CV-06373))
(N.D.N.Y. No. 05-CV-00397))	*County of Schuyler v. Abbott Labs., et al.*)
County of Cayuga v. Abbott Labs., et al.)	(W.D.N.Y. No. 05-CV-06387))
(N.D.N.Y. No. 05-CV-00423))	*County of Chemung v. Abbott Labs., et al.*)
County of Madison v. Abbott Labs., et al.)	(W.D.N.Y. No. 05-CV-06744))
(N.D.N.Y. No. 05-CV-00714))	*County of Steuben v. Abbott Labs., et al.*)
County of Cortland v. Abbott Labs., et al.)	(W.D.N.Y. Case No. 05-CV-6223))
(N.D.N.Y. No. 05-CV-00881))	*County of Wyoming v. Abbott Labs., et al.*)
County of Ulster v. Abbott Labs., et al.)	(W.D.N.Y. Case No. 05-CV-6379))
(N.D.N.Y. Case No. 06-CV-0123))	

PRELIMINARY STATEMENT

The claims the New York Counties allege against Merck are based on the difference between the prices at which Medicaid providers (mostly pharmacies) acquire Merck drugs and the published AWPs used as reimbursement benchmarks. That difference has been referred to as the "spread," and the Court repeatedly has ruled that spreads below a certain level are not actionable or are so unlikely to be actionable that discovery as to them should be stayed.[1] For the last five years, the Counties have tried out various forms of mathematical gymnastics designed to yield "spreads" that would exceed the Court's thresholds in order to support discovery and keep the cloud of litigation over drugs excluded from discovery by the Court.[2]

Plaintiffs' Motion to Compel Discovery from Defendant Merck & Co., Inc. ("Motion to Compel") represents the Counties' latest attempt to get around the Court's discovery stay order and defeat the Court's effort to simplify issues. In the revised exhibits to their First Amended Consolidated Complaint ("FACC"), Plaintiffs attempted to allege spreads in excess of 30% for 17 Merck drugs. Merck objected that Plaintiffs had not used "weighted average, or typical, price[s] . . . calculated on a reasonable good faith basis" consistent with the Court's prior orders, as explicitly required by Case Management Order No. 33 ("CMO 33"), to allege spreads greater

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[1] *See, e.g.*, *In re Pharm. Wholesale Price Litig.*, 498 F. Supp. 2d 402, 405 (D. Mass. 2007). The Plaintiffs' Consolidated Complaint acknowledged the "generally accepted" 1.2 or 1.25 markup by First DataBank and other publishers, and stated "this case is not about the 20-25% mark up between WAC and AWP." ([Corrected] Consolidated Compl. ¶ 7, June 15, 2005.)

[2] *See, e.g.*, Mem. & Order, Apr. 8, 2005 [Docket No. 1482] (describing the original methodology used by Suffolk County to calculate spreads and dismissing based on its inadequacy); Mot. to Dismiss Hr'g Tr., at 6-8, July 26, 2007 (addressing Counties' use of penny transactions to calculate spreads) [Docket No. 4519] (Ex. 1 to the Declaration of Robert B. Funkhouser); Defs.' Mem. In Supp. of Joint Mot. to Exclude Proffered Expert Report and Test. of Harris Devor, C.P.A., at 4-9, 17-19, June 15, 2009 [Docket No. 6127] (highlighting the fundamental flaws in the methodology employed by the Counties' expert, Harris Devor, in his FUL calculations).

than 30% for several Merck drugs. (CMO 33 ¶ 2(b), Sept. 14, 2007 [Docket No. 4745].) Merck produced documents and other discovery related to other drugs and general matters, but limited or withheld discovery with respect to the drugs subject to its objections.

Plaintiffs now move to compel discovery, arguing they can now establish that certain of the alleged spreads met CMO 33's requirements. The device they use for this purpose is the substitution of Average Manufacturer Price ("AMP")[3] for the proper measure − average or typical provider acquisition costs − to calculate AWP spreads. This attempt to move the goal post should be rejected for two reasons:

First, although AMP may provide a useful, conservative check on Plaintiffs' use of wholesaler data, AMP is not an appropriate proxy for provider acquisition costs for self-administered brand drugs, such as virtually all of the Merck drugs at issue here. Rather, AMP is derived from manufacturers' sales ***to*** wholesalers and necessarily will be less than average or typical prices paid by providers where they acquire drugs ***from*** wholesalers, typically by ***at least*** 3 to 5%.[4] Plaintiffs' use of AMP-to-AWP spreads that slightly exceed 30% to argue they have demonstrated spreads meeting CMO 33's criteria in fact proves the opposite. Far from validating Plaintiffs' spread allegations, the Counties' own data and analysis show that the spreads alleged in the FACC were not "calculated on a reasonable good faith basis." For example, in the FACC, Plaintiffs alleged a spread of 345% for a formulation of the drug MEVACOR®, but the highest AMP-to-AWP spread the Counties' expert now calculates for the same NDC is 30.52%. Similarly, Plaintiffs alleged a spread of 97% for a formulation of the drug

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[3] AMP is defined by federal statute. 42 U.S.C. § 1396r-8(k)(1)(A) (2006).

[4] In fact, the difference between provider acquisition costs and AMP will often be greater since AMP may include rebates to entities that are not reimbursed by Medicaid and payments to wholesalers in respect of chargebacks that play no role in the sale of drugs to the relevant Medicaid providers.

COZAAR® in 2004, but the AMP-to-AWP spread the Counties' expert now calculates for the same NDC for that year is 31.47%. Given the nature of AMP, the Counties' cataloging of Merck drugs with apparent AMP-to-AWP spreads barely above 30% succeeds only in establishing that the spread allegations in Plaintiffs' Complaint were not in good faith and that discovery as to these Merck drugs should continue to be stayed.

Second, even if AMP-to-AWP spreads theoretically could be used to satisfy CMO 33's criteria, the Counties' expert, Mr. Harris Devor, employs a systematically biased, inaccurate, and unreliable methodology to overstate even the AMP-to-AWP spreads (which already overstate the spreads relevant to the litigation). Mr. Devor's approach to deriving AMP-to-AWP spreads compares AWPs, whenever they are adjusted, to AMPs that are reported on a quarterly basis, without accounting for the comparison of a price from before a price change to a price from after such a change. To generate spreads in excess of 30%, he further cherry-picks particular periods to increase the AMP/AWP differential. The Court permitted the Counties to propose an alternative calculation of spreads, but warned that it must be "transparent and consistent in its methodology." (Order, Sept. 22, 2008 [Docket No. 5605].) Mr. Devor's methodology fails to meet that standard. The Counties' motion should accordingly be denied in its entirety.

BACKGROUND

Plaintiffs' unsuccessful attempts to find actionable spreads for Merck's and other manufacturers' drugs began at the outset of this litigation. Suffolk County sued first, and the Court found inadequate its technique for calculating the spread between actual wholesale prices

to providers and published AWPs.[5] (Mem. & Order, Apr. 8, 2005 [Docket No. 1482].) After allowing other New York counties to plead their claims in a consolidated complaint, the Court denied Defendants' motion to dismiss only as to those drugs for which the Counties could plead, among other things, "an allegedly fraudulent AWP calculated on a good faith basis, together with a spread," based on "a good faith estimate of an 'actual' market price from which the spread may be calculated." *City of New York, et al. v. Abbott Labs., et al.*, Civ. Action No. 01-12257-PBS, 2007 WL 1051642, at *14-*15 (D. Mass. Apr. 2, 2007).

In the original exhibit to their First Amended Consolidated Complaint, Plaintiffs calculated "spreads" by comparing AWP with the single lowest price paid by a purchaser to a wholesaler at any time. (*See* Pls.' Mem. of Law in Opp. to Defs.' Joint Mot. to Dismiss FACC, at 2-3, July 11, 2007 [Docket No. 4452].) At the hearing on Defendants' motion to dismiss that complaint, the Court again made clear that spreads must be based on "good faith" calculations of the prices available from wholesalers to providers; counsel for the Counties agreed. (*See* Ex.1 (July 26, 2007 Hr'g Tr., at 22:23-23:9).)[6] In its Case Management Order No. 33, the Court stayed discovery on all drugs as to which the Counties failed to plead such good faith spreads greater than 30%, directing in relevant part that:

> 2. (b) [Plaintiffs] shall allege a weighted average, or typical, price for each drug calculated on a reasonable good faith basis consistent with ¶ 5 of this Court's July 30, 2007 order and prior opinions.
>
> (c) any NDC for which the percentage difference between the weighted average, or typical, wholesale price alleged by plaintiffs and the published Average Wholesale Price ("AWP") for that NDC is 30% or less

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[5] In that same Order, the Court dismissed Suffolk County's claims against Merck and the other "Suffolk 13" defendants. (Mem. & Order, Apr. 8, 2005 [Docket No. 1482].)

[6] References to exhibits are to the exhibits to the Declaration of Robert B. Funkhouser, filed herewith.

> shall be moved from FACC Exhibit B-1 and placed in an amended FACC Exhibit B-2;
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> * * *
>
> 4. Discovery is stayed as to all NDCs appearing in new FACC Exhibits B-2 and B-4 until such time as the plaintiffs submit an expert affidavit providing a good faith basis for a 20-25% spread threshold.

(CMO 33, Sept. 14, 2007 [Docket No. 4745].)

The Counties filed several iterations of revised FACC exhibits, and filed the operative exhibits on September 28, 2007. (Revised FACC Ex. B [Docket No. 4754].) The Counties listed the Merck drugs for which they seek to pursue claims in Exhibit B-24 and, in partial compliance with CMO 33,[7] divided those drugs into those alleged to have spreads of 30% and above, and those alleged to have spreads between 25% and 30%.

Shortly after receiving the Counties' Exhibit B-24, Merck prepared a detailed letter to Plaintiffs' counsel setting forth Merck's objections and concerns regarding Plaintiffs' spread allegations and otherwise challenging the inclusion of several Merck drugs on the list of those purportedly subject to discovery. (*See* Ex. 2 (Oct. 12, 2007 Letter from R. Funkhouser to J. Cicala).) Merck's objections included:

- With respect to nine NDCs on the list, Plaintiffs alleged spreads of exactly 30%, even though CMO 33 clearly provided that NDCs with spread of "30% or less shall be moved" to the exhibit listing NDCs as to which discovery is stayed. CMO 33 ¶ 2(c). For 3 of the 20 Merck drugs listed by Plaintiffs as subject to discovery, the only NDC identified by Plaintiffs was one for which Plaintiffs alleged exactly a 30% spread.[8]

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[7] Under CMO 33, the Counties were to file one exhibit for drugs with alleged spreads greater than 30% and a separate exhibit for drugs with spreads of 30% or less. Instead, the Counties filed a single exhibit containing two lists for each defendant and, as explained below, included drugs with alleged spreads of exactly 30% on the same list as drugs with alleged spreads of greater than 30%.

[8] As used herein, the term "drug" is meant to refer to all formulations and package sizes of a named drug product, as opposed to the term "NDC," which refers to a single formulation and – in the case of the 11-digit NDCs used by the Counties in Exhibit B-24 – package size. A single drug will generally have multiple NDCs, and several Merck drugs have NDCs appearing on both lists in Exhibit B-24. A great

(Footnote continued on next page)

- Plaintiffs selected time periods over which to calculate the spreads to artificially maximize the apparent spread. Plaintiffs used many very short and atypical time periods to derive spreads appearing to equal or exceed 30%. For example, the spreads for 12 of the NDCs are based on wholesaler transactions occurring on a single day – December 31, 2002. Plaintiffs calculated the spreads for numerous other NDCs based on time periods of just a few days.

- Plaintiffs selected time periods during which published AWPs increased and Plaintiffs then compared the post-increase AWP to wholesaler sales that were based on pre-increase prices.

- Certain spreads – particularly where Plaintiffs used very short periods of time – were based on very few transactions, exaggerating differences based on classes of trade and non-representative customers.

(*See id.*) In addition, Merck pointed out that, for a number of drugs included on Exhibit B-24, there was minimal aggregate utilization for all of New York State for the time periods chosen by the Counties. Indeed, for some drugs, the quarterly reimbursement data provided by New York Medicaid to CMS reflected no utilization whatsoever in the time periods Plaintiffs used to calculate spread.[9] Moreover, since each County is a separate Plaintiff, the low aggregate utilization for the entire State made it unlikely that a particular litigating county paid any reimbursements during the short time periods cherry-picked by the Counties for their spread calculations. (*See id.*)

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deal of the discovery sought by Plaintiffs can be responded to only at the level of drugs, rather than NDCs.

[9] Claims data had not been produced at the time of Merck's letter. Accordingly, Merck used utilization data obtained from the CMS website for the entire State of New York, including those counties which have not sued Merck, Suffolk County (as to which claims against Merck and others of the "Suffolk 13" have been dismissed) and counties represented by other counsel that have sued in state court. As pointed out in Merck's letter, these aggregate state reimbursement amounts substantially overstate the amounts at issue. The reimbursement data include dispensing fees, and also reflect aggregate reimbursement for both the state and federal shares, rather than just the roughly 25% attributable to the counties. The CMS data also does not reflect the reduction in reimbursement resulting from federal rebates of at least 15.1 percent of AMP.

Plaintiffs responded by rejecting each and every one of Merck's proposals to narrow the drugs at issue for discovery. (*See* Ex. 3 (Oct. 18, 2007 Letter from J. Cicala to R. Funkhouser).) After a lengthy meet and confer by telephone, these differences were not resolved or narrowed. In January and February 2008, Merck produced (1) responsive documents that were not drug-specific and (2) documents and AMP data relating to the drugs on Ex. B-24 to which Merck had not objected.

For 17 months, Merck received no further communications on the drugs at issue.[10] Then, on July 29, 2009, Plaintiffs requested that Merck (1) produce additional depositions taken in other AWP cases after Merck's prior production; (2) allow use for litigation purposes of AMP data for Merck drugs, including for those drugs stayed pursuant to CMO 33, that Merck had provided to Plaintiffs in the course of mediation, and (3) produce all discovery provided by Merck to states represented by the Miner Barnhill firm, including an extract from a database. (Ex. 4 (July 29, 2009 Letter from J. Cicala to R. Funkhouser).) Merck objected to providing Plaintiffs with documents related to drugs stayed by CMO 33, but agreed to supplement its production with depositions and written documents related to the drugs not stayed by CMO 33, or to which Merck's other objections did not apply. (Ex. 5 (Aug. 4, 2009 Letter from R. Funkhouser to J. Cicala).) Merck also later agreed that Plaintiffs could use the AMP data from the mediation. Merck produced the requested depositions and exhibits taken in other AWP cases on August 19, 2009, and produced additional documents on September 15, 2009.[11]

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[10] The only drug relevant to the expedited discovery of FUL drugs had been divested by Merck prior to the FUL being established and the parties stipulated to its exclusion from FUL discovery. (Stipulation Regarding FUL Disc. of Def. Merck & Co., Inc., Apr. 23, 2008 [Docket No. 5249].)

[11] In the section of Exhibit B-24 titled "Merck NDCs at Issue With Spreads of 30% and Above" Plaintiffs identify NDCs for 20 Merck drugs. However, 3 Merck drugs had alleged spreads of exactly

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Plaintiffs filed their motion to compel, arguing that AMP-to-AWP spreads in excess of 30% calculated by their CPA, Harris Devor, showed that 130 Merck NDCs – only 121 of which were listed on FACC Revised Exhibit B-24 – met the CMO 33 threshold and that discovery should therefore be allowed as to all drugs in that Exhibit and in the Exhibit to Mr. Devor's Declaration.[12]

ARGUMENT

"if you torture numbers long enough, they will confess to anything."[13]

Far from validating the Counties' previous allegations of spreads between provider acquisition cost and AWP that exceed 30 percent, Mr. Devor's AMP-to-AWP spreads demonstrate that most of the spreads for Merck drugs in Exhibit B-24 cannot be alleged in good faith. Although Mr. Devor calculates a few anomalous spreads, the overwhelming majority of the AMP-to-AWP spreads calculated by Mr. Devor are below 35%. (*See* Ex. 8 (Affidavit of Eric M. Gaier, Ph.D. ("Gaier Affidavit")).) The decisions and orders of this Court, statutory definition and federal guidance on AMP, and a close examination of Mr. Devor's methodology

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30% and are thus not subject to discovery according to CMO 33 ¶ 2(c). Merck has produced documents for 7 of the remaining 17 drugs.

[12] Of the 130 unique NDCs for which Mr. Devor calculated AMP-to-AWP spreads, only 58 are listed in Exhibit B-24 to the Complaint among the 82 NDCs alleged to have spreads of 30% and above. Sixty-three NDCs included in Devor Exhibit A are listed on Exhibit B-24 to the Complaint as having spreads below 30%. Nine NDCs in Devor Exhibit A appear nowhere in Exhibit B-24 to the Complaint. Under CMO 33, the Counties have no basis for seeking discovery with respect to any Merck NDCs other than those for which they alleged spreads greater than 30% in Exhibit B-24 to the Complaint. Attached as Exhibit 6 to the Declaration of Robert B. Funkhouser is a chart listing the NDCs in Mr. Devor's Exhibit A and where each appears in Exhibit B-24 to the Complaint, if at all.

[13] Gregg Easterbrook, The Progress Paradox: How Life Gets Better While People Feel Worse 10 (2004).

confirm that Plaintiffs have failed to allege good faith spreads between AWP and provider acquisition cost, as required by the Court. The motion to compel should be denied.

I. The Counties' Calculations Of AMP-To-AWP Spreads Do Not Validate The Allegations Of Merck Spreads Greater Than 30% In Exhibit B-24

A. The Relevant "Spread" Is Between Provider Acquisition Cost And AWP

Since the inception of this litigation, the parties and the Court have used "spread" to refer to the difference between some measure of Medicaid provider acquisition costs and the published AWP (or the reimbursement amount based on AWP).[14] CMO 33 explicitly defines the 30% discovery cut-off in terms of a spread "between the weighted average, or typical, wholesale price alleged [in good faith] by plaintiffs and the published Average Wholesale Price ('AWP')." (CMO 33 ¶ 2(c).)

Contrary to the premise of Plaintiffs' motion, the Court's September 22, 2008 Order – which affirmed and modified Magistrate Judge Bowler's decision granting Schering Corporation's motion for a protective order as to its branded drugs – does not render AMP-to-AWP spreads appropriate substitutes for the spreads described in CMO 33. Instead, consistent with Schering's argument, the Court simply accepted that AMP data could provide a conservative check on the outlier prices and cherry-picked time periods in the Counties' FACC spread allegations. (*See* Schering Corp.'s Mem. In Supp. Of Its Mot. For Protective Order, at 7, May 13, 2008 [Docket No. 5297].) Merck did not request that its AMPs be used to test the

[14] *See, e.g.*, Revised First Am. Consolidated Compl. ¶ 16, Oct. 5, 2007 [Docket No. 4780] ("Defendants submit false and inflated price information to the publishing compendia in order to 'create a spread' between the AAC [actual acquisition cost] of a drug and the amount at which the drug is reimbursed."); [Corrected] Consolidated Compl. ¶ 9, June 15, 2005 ("The 'spread' is the difference between the actual acquisition cost of a drug and the amount at which the drug is reimbursed."); Pls.' Objections to Aug. 20, 2008 Ruling By Magistrate Judge Bowler Granting Schering Corp.'s Mot. For A Protective Order, at 1, Sept. 4, 2008 [Docket No. 5546] (requesting guidance "as to what constitutes good faith when pleading actionable spreads based on a weighted average of wholesaler prices").

Counties' spread allegations and the Court did not purport to modify CMO 33 to permit AMP to be substituted for provider acquisition costs in the calculation of the relevant spread. The Court's September 22, 2008 Order allows AMP to be used as a shield, not as a sword. As explained below, that distinction flows logically from the different characteristics of AMP and provider acquisition costs.

B. AMPs Are Not Appropriate Proxies For Provider Acquisition Cost For Merck Drugs And Their Use Overstates The AWP Spreads

"Spread" is relevant to quantify the difference between Medicaid providers' acquisition costs – *i.e.*, what providers pay wholesalers – and the Medicaid reimbursement benchmark for those providers – *i.e.*, AWP (less a percentage). But AMP does not measure the prices paid *by providers to wholesalers*. Instead, AMP measures the prices paid *by wholesalers to manufacturers* in certain transactions and subject to certain qualifications. A federal statute defines AMP as "the average price *paid to the manufacturer* for the drug in the United States *by wholesalers* for drugs distributed to the retail pharmacy class of trade." 42 U.S.C. § 1396r-8(k)(1)(A) (2006) (emphasis added).[15] By definition, since wholesalers may be presumed to charge more for a drug than they pay for it, comparing AMP to AWP overstates spreads between provider acquisition cost and AWP.

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[15] The Deficit Reduction Act of 2005 ("DRA") amended the federal rebate statute and its definition of AMP. Pub. L. 109-171, § 6001(c) (2006). Among the changes was the exclusion from AMP of manufacturers' prompt payment discounts, which had previously been included in the AMP calculation. *Id.* § 6001(c)(1). Congress also directed CMS to promulgate regulations providing additional guidance on the calculation and use of AMP. The effective date of the DRA's changes to AMP post-dates the relevant time period in this litigation.

1. AMP-to-AWP Spreads Overstate Spreads Between Provider Acquisition Costs And AWP By ***At Least*** 3 To 5 Percentage Points

AMP is a measure of prices paid by wholesalers to a manufacturer, while provider acquisition cost and weighted average or typical wholesale price measure prices paid by providers to wholesalers. Because wholesalers sell drugs for higher prices than they pay to acquire them, average or typical provider acquisition costs for a drug inevitably will exceed the drug's AMP. The existence of wholesaler markups means using AMP will overstate spreads between provider acquisition costs and AWP, particularly when the purpose of using AMPs is to quantify spreads within a few (or, as with many Merck NDCs, mere fractions of) percentage points.

In his independent expert report to the Court, Professor Berndt canvassed the literature on pharmaceutical pricing and quoted an academic's description of the typical wholesale mark-up for branded, self-administered drugs as 2.5%. (Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris ¶ 22, Feb. 9, 2005 [Docket No. 1383] (quoting Mick Kolassa, *Guidance for Clinicians in Discerning and Comparing the Price of Pharmaceutical Agents*, J. of Pain & Symptom Mgmt. 235-243 (May 1994).) Other sources indicate that wholesalers typically apply larger markups, such as 4%.[16] This widespread understanding that provider acquisition costs exceed AMP is recognized in the Medicare Part B program. Reimbursements for physician-administered drugs under Medicare Part B are in certain circumstances made at the lower of "widely available market price" or 103% of AMP. 42 U.S.C. § 1395w-3a(d)(3)(c).

[16] Dep't of Health & Human Servs., Report to the President on Prescription Drug Coverage, Utilization, and Prices 101 (Apr. 2000), *available at* http://aspe.hhs.gov/health/reports/drugstudy/ (noting that "[t]he markup added by the wholesaler is generally small, perhaps 2 percent to 4 percent"); *FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d. 34, 40 (D.D.C. 1998) (four percent).

This alternative reimbursement formula makes sense only if Congress understood that market prices available to providers typically exceed AMP by at least 3%.

Assuming that AMP reflects the average price paid by wholesalers for a drug that will be sold to a Medicaid provider,[17] a 30.1% AMP-to-AWP spread would correspond to at most a 26.9% spread between provider acquisition cost and AWP if the wholesaler markup is 2.5%, and would correspond to at most a 25.1% spread if the wholesaler markup is 4%.[18] An AMP-to-AWP spread that just barely exceeds 30%, therefore, necessarily reflects a spread between provider acquisition cost and AWP that is at least several percentage points below the 30% threshold set by the Court.

Wholesaler markups demonstrate why the Court's ruling granting Schering's Motion for a Protective Order as to drugs with AMP-to-AWP spreads under 30% (calculated on a more reasonable basis than Mr. Devor used) does not support the Counties' motion to compel as to Merck drugs for which Mr. Devor calculates AMP-to-AWP spreads just over 30%. Schering established that a single-source drug with an AMP-to-AWP spread of no more than 30% could not have a spread between average provider acquisition cost and AWP of more than 30%. This does not mean that an AMP-to-AWP spread greater than 30% is *likely* to have a greater-than-

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[17] In fact, as discussed below, AMP will typically be less than the average price paid by wholesalers for drugs sold to Medicaid providers. Indeed, apart from potential short-term anomalies, there is no plausible set of circumstances where a drug's AMP will be consistently higher than a weighted average of prices paid by wholesalers that resell that drug to Medicaid providers. Accordingly, the assumption that provider acquisition costs exceed AMP by the amount of the wholesaler markup is exceedingly conservative.

[18] To illustrate, if the AMP for a drug is $100 and the AWP for that drug is $130, the AMP-to-AWP spread is exactly 30%. Assuming that wholesalers purchase that drug from manufacturers at AMP and then apply, on average, a 4% markup over their cost, the average prices paid by providers to wholesalers is $104. The "spread" between average provider acquisition cost would be 25% (*i.e.*, ($130 - $104)/$104), which is well below the 30% discovery threshold.

30% spread between provider acquisition cost and AWP. Indeed, because of wholesaler markups, it is highly *improbable* that drugs with AMP-to-AWP spreads within a few percentage points of 30% have spreads (as the Court used the term) greater than 30%.

2. Other Aspects Of AMP Make It An Inappropriate Proxy For Provider Acquisition Cost For Merck Drugs

The federal government and virtually every interested market participant agree that other aspects of AMP calculations create further distance between AMP and provider acquisition cost. (*See* Ex. 7 (Dep't of Health & Human Servs., Office of Inspector Gen., Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005 (May 2006) [hereinafter "May 2006 OIG Report"]).)[19]

The May 2006 OIG Report attaches detailed comments from industry groups and the federal government. Although these entities have sometimes diverging interests and perspectives, all agreed on the basic propositions expressed by the Generic Pharmaceutical Association:

> [F]luctuating order patterns and erratic timing of transactions result in unpredictable fluctuations in AMP from month to month, or quarter to quarter based on customer mix, discount payments, returns and other normal business transactions. Moreover, given the ambiguity in the current regulatory guidance for calculating AMP, different manufacturers may very well be employing different assumptions either on their own or in conjunction with regulatory counsel to calculate their respective AMPs, which results in a variability across AMPs that prevents a true apples-to-apples comparison of pricing data across manufacturers.

(*Id.* at App. B, 1-2.) The National Association of Chain Drug Stores agreed that AMP data "have wide variability in their meaning, and are likely unreflective of the approximate prices

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[19] The Report analyzes AMP calculation and reporting under the regulatory scheme in place prior to the DRA (including during the time period relevant to this litigation) in an attempt to provide guidance on how that scheme could be improved under the DRA's mandates. (*Id.* at 1-3.)

paid by retail pharmacies for prescription medications." (*Id.* at App. D, 4.) The National Community Pharmacists Association expressed the same view in stronger terms: "*AMP data is not at all likely to reflect the prices at which retail pharmacies purchase drugs.*" (*Id.* at App. E, 2 (emphasis added).) Even CMS – albeit in more restrained tone – "acknowledge[d] that the OIG has reported some confusion among drug manufacturers about what sales and price concessions must be included when calculating AMP. This is an extremely complex and technical topic that has been made more difficult due to changes in the chain of sales and the evolution of new entities, especially PBMs." (*Id.* at App. G, 2.)

Although the May 2006 OIG Report and its Appendices identify numerous shortcomings in the guidance applicable to manufacturers' AMP calculations, two problems in particular – the types of transactions to be included in AMP and time lags in the realization of discounts – relate to the AMP-to-AWP spreads calculated by Mr. Devor, further demonstrating why his AMP-to-AWP spreads do not meet CMO 33's standards for alleging relevant spreads.

As the OIG explained in its May 2006 Report, a consistent complaint from industry participants since the inception of the AMP-based rebate system is the limited and opaque guidance as to which transactions should be included in the calculation of AMP. (*Id.* at 4-5.) In reviewing several prior studies of which transactions manufacturers included in their AMP calculations, the OIG found almost as many different methodologies as there were participating manufacturers. (*Id.*) The idea that AMP provides a basis for transparent and consistent calculations of spreads was thus exploded years ago. For example, AMP calculations may include discounts to PBMs and other entities for which retail pharmacies are not generally eligible. Such discounts have no effect on the acquisition costs of Medicaid providers. When

they are included in AMP calculations – as OIG indicated they frequently are – those discounts add to the already substantial gap between AMP and provider acquisition costs.

The OIG reported that "the timing of price concessions and returned goods could create inconsistent AMPs from one period to the next." (*Id.* at 10.) When a manufacturer sells a drug in one quarter and pays a rebate in a subsequent quarter, the sale and rebate may be reflected for AMPs in two different quarters. (*See* Gaier Affidavit ¶ 10 & n.10.) When sales and price concessions are consistent between quarters, this lag is unlikely to have a substantial effect on AMP. When, however, the sales volume for a drug abruptly declines – because, for example, of patent expiration, generic entry, new therapeutic competition, or divestiture – from one quarter to the next while the effects of price concessions (*i.e.*, the obligation to pay rebates) continue at pre-decline levels, the drug's AMP may fall. (*Id.*) This effect is entirely an artifact of the AMP calculation methodology and does not reflect prices at which providers acquire drugs. The fact that AMPs are subject to substantial fluctuations that do not reflect corresponding fluctuations in provider acquisition costs further demonstrates that AMP understates provider acquisition costs and overstates the relevant spreads.

II. Even If AMP-To-AWP Spreads Theoretically Could Satisfy CMO 33's Requirements, Plaintiffs' Methodology For Calculating Such Spreads Does Not

A. Mr. Devor's Methodology And Conclusions Are Not Sound

Even if it were conceptually sound to accept AMP-to-AWP spreads in excess of 30% as sufficient to satisfy the discovery threshold set in CMO 33 (and it is not), the Counties would still need to employ a reliable, transparent, and consistent methodology in calculating those spreads. (*See* Order, Sept. 22, 2008.) Although Mr. Devor's explanation of his methodology for calculating AMP-to-AWP spreads may appear straightforward, the simplicity of the calculations does not render them sound. AMP is complex. AMP differs from AWP in numerous ways that

must be accounted for to derive meaningful and consistent comparisons between the two figures. Mr. Devor does not fairly account for the complexities of AMP and its differences from AWP, particularly with respect to the time periods used for reporting AMP and the different effects of price changes on AWP and AMP. Instead, the rudimentary formula he selectively applies appears calculated to yield elevated annual AMP-to-AWP spreads.

The most glaringly erroneous statement that the Counties make about Mr. Devor's calculations is that "plaintiffs' expert has determined that ***most*** spreads between Merck's AMPs and published AWPs (for those NDCs for which plaintiffs have Merck AMPs) are ***consistently*** over 30% on an annual basis." (Pls.' Mem., at 2 (emphasis added).) This is not correct. (Gaier Affidavit ¶¶ 6-8.) The majority of the NDCs on Mr. Devor's Ex. A – 77 of 130 – have average day-weighted AMP-to-AWP spreads below 30% over the entire time period. (*See* Gaier Affidavit ¶ 9.) Even as to those drugs, only 26 NDCs have AMP-to-AWP spreads of 32% or more, and most (22) of those are formulations of two drugs – ZOCOR® or a rarely reimbursed vial formulation of PEPCID®[20] – that have AMP-to-AWP spreads that (with one exception) remain below 40%. (Gaier Affidavit Attachment B.) If the AMP data show anything, it is that the overwhelming majority of Merck's drugs clearly fall under the 30% threshold for discovery.

Mr. Devor's methodology suffers from further fatal defects based on his selection and treatment of time periods. As Mr. Devor and the Counties are well aware, AMP during the relevant time period was reported on a quarterly basis, whereas AWP could – and typically did – change at mid-quarter. Mr. Devor compares the post-increase AWP with the quarterly AMP without any adjustment for the fact that the AMP includes transactions that occurred before the

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[20] Three of the remaining four NDCs with AMP-to-AWP spreads above 32% are NDCs that were not on Plaintiffs' Exhibit B-24, and are thus not part of the case. The remaining NDC with an AMP-to-AWP spread above 32% is a formulation of MEVACOR®.

AWP increase and lagged price concessions. By including time periods in which an AWP increase occurred, Mr. Devor captures artifacts of the AMP reporting system rather than real or consistent relationships between AMP and AWP.

Mr. Devor's calculations suffer from numerous additional defects that skew his results towards higher spreads. For example, he does not weight his averages based on transaction or expenditure volume. Failing to consider transaction volume distorts the comparison between AMP and AWP because the former is a weighted figure and the latter is not. Thus, if there are more transactions prior to an AWP increase, AMP will reflect that higher volume, but AWP will not. The result, of course, is a higher apparent spread that has no connection with the reality of the marketplace.

If there is a place for AMP in evaluating Plaintiffs' allegations of spreads, as the Court has made clear, the calculations must be "transparent and consistent." (Order, Sept. 22, 2008.) Mr. Devor's calculations do not meet that standard.

B. Mr. Devor's Spread Calculations Establish That The Counties' Spread Allegations In Exhibit B-24 Do Not Comply With CMO 33

An AMP-to-AWP spread in excess of 30% – even if calculated using a sound methodology – does not establish that the spread between provider acquisition cost and AWP also exceeds 30%. Because an AMP-to-AWP spread will necessarily be higher than the relevant spread for the same drug and time period, AMP-to-AWP spreads of sufficiently small magnitude do rule out a good faith basis for alleging spreads that meet the threshold established by CMO 33.[21] The overwhelming majority of the AMP-to-AWP spreads calculated by Mr. Devor for

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[21] *See* Schering Corp.'s Mem. In Supp. Of Its Mot. For Protective Order, at 6-7, May 13, 2008 [Docket No. 5297] (explaining the conservative nature of AMP-based spreads as a discovery screen).

Merck drugs exceed 30% by very small margins and for very limited periods of time. If those spreads establish anything, it is that the enormous spreads for certain Merck NDCs Plaintiffs alleged in Exhibit B-24 have no good faith basis.

For example, the largest spread alleged in Ex. B-24 is 345% for Mevacor 20 mg. The highest spread Mr. Devor was able to generate for that NDC using AMP data is 30.52%. The next highest is Cozaar 25 mg, for which B-24 alleges a spread of 316% from January 1, 2004 to May 28, 2004, but for which Mr. Devor calculates the AMP-to-AWP spread for 2004 to be 31.04%. Indeed, there are no AMP-to-AWP spreads in Mr. Devor's figures even approaching the magnitudes of many of the spreads contrived by Plaintiffs in Ex. B-24. Mr. Devor included only those NDCs and time periods for which he was able to find an apparent AMP-to-AWP spread greater than 30%. Even then, more than 97% of the expenditures covered by the NDCs selected by Mr. Devor were for NDCs and time periods for which Devor calculated AMP-to-AWP spreads of 35% or less. (*See* Gaier Affidavit, Fig. 1.) And an AMP-to-AWP spread of 35% or less is highly unlikely to reflect a spread between AWP and actual wholesaler prices to providers of more than 30%, as required by CMO 33.

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' Motion to Compel.

REQUEST FOR ORAL ARGUMENT

Pursuant to Local Rule 7.1(d), the undersigned counsel hereby request oral argument on the issues set forth in this Opposition to Plaintiffs' Motion to Compel.

Dated: October 5, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that, on October 5, 2009, I caused a true and correct copy of the foregoing document to be delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Robert B. Funkhouser
Robert B. Funkhouser